

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA)	
PHARMACEUTICAL COMPANY LTD.,)	
TAKEDA PHARMACEUTICALS U.S.A.,)	
INC., TAKEDA PHARMACEUTICALS)	
INTERNATIONAL AG and TAKEDA)	
PHARMACEUTICALS AMERICA, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 18-88 (LPS)
v.)	CONSOLIDATED
)	
ALKEM LABORATORIES LTD., et al.,)	REDACTED - PUBLIC VERSION
)	
Defendants.)	

**LETTER TO THE HONORABLE LEONARD P. STARK
FROM MEGAN E. DELLINGER REGARDING RESPONSE TO
DEFENDANTS LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S
MOTION TO EXPEDITE TO ENFORCE THIS COURT'S PRIOR ORDER AND
RENEWED MOTION TO STRIKE PORTIONS OF PLAINTIFFS' EXPERT REPORTS**

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Dear Chief Judge Stark:

Plaintiffs submit this response letter opposing Defendants Lupin Limited and Lupin Pharmaceuticals, Inc.’s (collectively, “Lupin”) Motion To Expedite To Enforce this Court’s Prior Order and Renewed Motion To Strike Portions of Plaintiffs’ Expert Reports (D.I. 899, 900). Citing no cases to support its position, Lupin argues that Plaintiffs have intentionally violated this Court’s Order by serving two reply experts reports discussing the results of analytical testing performed on samples of Lupin’s ANDA product. In so doing, Lupin ignores the contents of its own expert reports, which repeatedly claim that Lupin’s ANDA Product does not contain [REDACTED] of vortioxetine hydrobromide *whatsoever*. Lupin likewise ignores the meet and confer discussion where counsel for Plaintiffs explained that they were not offering the [REDACTED] evidence to support the [REDACTED] infringement theories stricken by this Court.

In reality, Lupin doesn’t seek to enforce this Court’s Order striking an infringement theory based on the [REDACTED] that Plaintiffs told Lupin they are not asserting. Instead, Lupin seeks a new order preventing Plaintiffs from (1) rebutting the factually incorrect testimony of Lupin’s experts, and (2) using evidence of crystallization as an item of proof to support its timely-asserted infringement claims. As set forth below, the order Lupin seeks is inconsistent with what this Court ordered and contrary to the Federal Rules. As a result, the motion should be denied.

I. Background

On March 6, 2020, Plaintiffs served Lupin with Final Infringement Contentions directed to: (1) claims 1, 2, 3 and 5 of the ’684 Patent; (2) claims 1, 2, 4, 5, and 7 of the ’355 Patent; (3) claims 1, 2, 4, and 5 of the ’946 Patent; and (4) claims 1-7 of the ’630 Patent.¹ Ex. 1 at 3 (Plaintiffs’ Final Infringement Contentions, Mar. 6, 2020). A few weeks later, expert testing revealed the presence of the [REDACTED] of vortioxetine hydrobromide in Lupin’s ANDA product. As a result, counsel for Plaintiffs informed counsel for Lupin that Plaintiffs intended to add new allegations that Lupin infringed [REDACTED]. Plaintiffs then addressed those claims in their opening expert reports.

On May 6, 2020, Lupin moved to strike the portions of Plaintiffs’ expert reports alleging “new patent claims directed to the [REDACTED].” D.I. 748 at 3. In so doing, Lupin explained that its “motion is intended to cover any opinion that Lupin *infringes based on the new infringement theory*.” D.I. 747 at 1 (emphasis added); *see also*, e.g., D.I. 748 at 4 (“III. The *Pennypack* Factors Favor Striking Plaintiffs’ *New Infringement Theory*” (emphasis added)). But Lupin never asked this Court to exclude [REDACTED] evidence being offered as an item of proof of Plaintiffs’ timely-asserted claims.²

¹ Plaintiffs also asserted claims related to the ’910, ’096, and ’628 Patents. Those claims, however, are not implicated by Lupin’s motion.

² Indeed, Lupin explained in its motion that it was not requesting to strike every highlighted portion of Plaintiffs’ opening expert reports attached to its motion for all purposes because those portions “may include opinions regarding other theories as well.” D.I. 747 at 1.

On June 25, 2020, this Court granted the motion to strike. D.I. 801. In so doing, this Court explained that Plaintiffs failed to give Lupin “fair and timely notice” of its intention to assert infringement “due to the presence of” the [REDACTED] of vortioxetine hydrobromide. *Id.* But this Court also ruled that Plaintiffs could freely “proceed on their other timely-asserted claims of infringement.” *Id.*

In response to Plaintiffs’ opening expert reports, Lupin submitted the rebuttal report of Dr. Jeremy Cockcroft on June 5, 2020. In it, Dr. Cockcroft opined that Lupin’s ANDA product is [REDACTED], including “a crystalline vortioxetine hydrobromide in the [REDACTED].” Ex. 2 (Cockcroft Rebuttal Report) ¶ 194; *see also id.* ¶ 123 (“Lupin’s submission of this data to FDA was accompanied by associated peak lists. Other than at the Drug Substance stage . . . none of the XRPD patterns or peak lists show peaks establishing the presence of [REDACTED]” (emphasis added)). To support that argument, Dr. Cockcroft analyzed the XRPD testing performed by Plaintiffs’ experts, and asserted that it demonstrates the stability of Lupin’s ANDA product because “[n]one of the unstressed samples tested by Dr. Morin generated XRPD diffraction patterns depicting [REDACTED]” *Id.* ¶ 107 (emphasis added).

Plaintiffs submitted reply reports on July 31, 2020. Consistent with this Court’s June 25, 2020 Order, Drs. Myerson and Morin offer no opinions regarding infringement of any claims by the [REDACTED]. Instead, Plaintiffs’ experts discussed the factual results of their testing—which observed [REDACTED]s, including the [REDACTED]—to: (1) reinforce Dr. Myerson’s arguments that Lupin’s ANDA product is [REDACTED], including the infringing (and timely-asserted) [REDACTED]; and (2) rebut Lupin’s incorrect claims that its product contains [REDACTED].

Ignoring the fact that reference to the [REDACTED] in Plaintiffs’ reply reports was in response to an argument in Lupin’s rebuttal expert reports, Lupin inaccurately accused Plaintiffs of “asserting a theory of infringement involving the [REDACTED]” in violation of this Court’s order. Ex. 3 (Aug. 5, 2020 email from J. Janusz to counsel of record for Plaintiffs). The parties met and conferred on August 10, 2020, and Plaintiffs explained that it was not offering the [REDACTED] evidence to support the [REDACTED] infringement theories stricken by this Court on June 25, 2020.³ Instead, counsel for Plaintiffs explained, the limited purpose of the [REDACTED] evidence was to rebut Lupin’s claim that it has a [REDACTED] (*i.e.*, [REDACTED]) that does not [REDACTED].

II. Legal Standard

Infringement contentions can be stricken if not timely disclosed under Rule 37(c)(1). *Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 13–1668–LPS, 2017 WL 658469, at *1 (D. Del. Feb. 14, 2017). By contrast, (1) items of proof of timely asserted claims, (2) rebuttal expert testimony, and (3) evidence that will be used “solely for impeachment” purposes are all exempt from disclosure under Rule 26. *See, e.g., Oracle Am., Inc. v. Google, Inc.*, Case No. 10–03561, 2011 WL

³ Plaintiffs, of course, disagree with this Court’s June 25 Order for the reasons set forth in the briefing on the issue. D.I. 799. But Plaintiffs have complied and will comply with that Order.

4479305, at *3 (N.D. Cal. Sept. 26, 2011) (holding that a party that adequately discloses a theory of infringement is not required to list in its contentions every “item of proof” that supports that theory); Fed. R. Civ. P. 26(a)(2)(D)(ii) (detailing the time to disclose expert testimony); Fed. R. Civ. P. 26(a)(1)(A) (exempting from initial disclosures evidence used “solely for impeachment.”). As a result, “[r]epley reports may cite new evidence and data so long as the new evidence and data is offered to directly contradict or rebut the opposing party’s expert.” *Helios Software, LLC v. SpectorSoft Corp.*, Case No. 12-081-LPS, 2014 WL 4796111, at *3 (D. Del. Sept. 18, 2014) (citation and internal quotation marks omitted).

III. Argument

Although Lupin claims it is seeking to enforce an Order this Court has already entered, in fact, the relief Lupin seeks goes far beyond what this Court ordered on June 25. Rather than seeking to preclude Plaintiffs from offering an infringement theory related to the [REDACTED] (as this Court ordered), Lupin seeks to preclude Plaintiffs from offering any evidence discussing the presence of the [REDACTED] of vortioxetine hydrobromide for any purpose whatsoever. That distinction is critical. Because the presence of any crystalline form—including the [REDACTED]—is relevant to rebutting Lupin’s experts and proving Plaintiffs’ timely-asserted claims directed to other crystalline forms, the [REDACTED] evidence that Plaintiffs’ experts offer is proper, timely, permitted by the Federal Rules, and not inconsistent with this Court’s June 25 Order. This Court should accordingly deny Lupin’s motion.

A. The [REDACTED] References in Plaintiffs’ Reply Expert Reports Are Proper Rebuttal Testimony.

Although Lupin complains about reference to the [REDACTED] in Plaintiffs’ reply reports, it ignores the context of the reply reports—to rebut Dr. Cockcroft’s rebuttal report, which repeatedly claims that Lupin’s ANDA Product does not contain [REDACTED]. Lupin could have argued that its ANDA product does not contain or convert to the [REDACTED]. Instead, however, Lupin’s crystalline chemistry expert—Dr. Cockcroft—broadly asserts that Lupin’s ANDA product is [REDACTED] of vortioxetine hydrobromide that does not convert to [REDACTED], including “a crystalline vortioxetine hydrobromide in the [REDACTED].” Ex. 2 ¶ 194. Having done so, Plaintiffs’ response to those factually incorrect statements should not be stricken.

“Rebuttal evidence is properly admissible when it will explain, repel, counteract or disprove the evidence of the adverse party” and it need not be disclosed until after the opposing party’s relevant disclosure. *Helios Software*, 2014 WL 4796111, at *3 (citations and internal quotation marks omitted); Fed. R. Civ. P. 26(a)(2)(D)(ii). As a result, “[r]epley reports may cite new evidence and data so long as the new evidence and data is offered to directly contradict or rebut the opposing party’s expert.” *Helios Software*, 2014 WL 4796111, at *3 (citation and internal quotation marks omitted).

Applying the rules regarding rebuttal testimony here, the [REDACTED] references in Plaintiffs’ reply reports are plainly permissible. Because testing showing presence of the [REDACTED] of vortioxetine hydrobromide contradicts Dr. Cockcroft’s claim that Lupin’s ANDA product does not convert to [REDACTED], it is proper rebuttal evidence,

which, as noted below, is relevant to the “timely-asserted claims of infringement” on which this Court ruled that Plaintiffs can proceed. D.I. 801; *Helios Software*, 2014 WL 4796111, at *3 (“Rebuttal evidence is properly admissible when it will explain, repel, counteract or disprove the evidence of the adverse party.” (citation and internal quotation marks omitted)). Although this Court’s Order precludes [REDACTED] evidence from being used to assert a theory of infringement involving the [REDACTED], Plaintiffs are not offering the [REDACTED] evidence for that impermissible purpose. As a result, the [REDACTED] evidence still can and should be admitted to rebut Dr. Cockcroft’s incorrect opinion.

B. References to the [REDACTED] in Plaintiffs’ Reply Expert Reports Are Proper Items of Proof of Plaintiffs’ Timely-Asserted Claims.

In addition to serving a proper rebuttal purpose, the [REDACTED] references in Plaintiffs’ reply expert reports are permissible items of proof of their timely-asserted [REDACTED] infringement claims. It is well-established that a party that adequately discloses a theory of infringement is not required to list in its contentions every item of proof that supports its theory. *Adobe Systems Inc. v. Wowza Media Sys.*, No. 11-cv-02243-JST, 2014 WL 709865, at *16 (N.D. Cal. Feb. 23, 2014) (“Because Adobe adequately disclosed this theory, Adobe was not required to list every bit of WMS source code that supports it.”); *Oracle*, 2011 WL 4479305, at *3 (holding that a party that adequately discloses an infringement theory is not required to list in contentions every “item of proof” that supports that theory). As a result, it may be proper to offer evidence supporting a timely infringement theory even if that evidence was not disclosed in infringement contentions.

In this case, there is no dispute that infringement of claims 1, 2, 3 and 5 of the ’684 Patent, claims 1, 2, 4, 5, and 7 of the ’355 Patent, claims 1, 2, 4, and 5 of the ’946 Patent, and claims 1-7 of the ’630 Patent by the [REDACTED] was timely disclosed. Having adequately disclosed those theories, Plaintiffs may prove them with any relevant items of proof that support their theory. Lupin’s arguments do not address the relevance of [REDACTED] evidence to Plaintiffs’ timely-asserted claims. But the presence of any crystalline form is relevant to Plaintiffs’ timely-asserted claims insofar as it: (1) demonstrates that Lupin’s [REDACTED]; and (2) proves the inadequacy of [REDACTED]. As a result, Plaintiffs’ experts properly offered [REDACTED] evidence to prove the [REDACTED] of Lupin’s ANDA product, because this [REDACTED] of Lupin’s ANDA product supports that Lupin’s product [REDACTED] (timely-disclosed) [REDACTED]

C. This Court Order Did Not Preclude Plaintiffs from Discussing the Results of Its Independent Testing for All Purposes.

Rather than addressing the law regarding the permissible contents of expert reports, Lupin claims that this Court’s Order precludes Plaintiffs from offering any evidence of the presence of the [REDACTED] for any purpose whatsoever. But that is not what the Court ordered and takes the June 25 dispute entirely out of context. That earlier dispute arose out of Plaintiffs’ assertion of [REDACTED] of the ’630 Patent, which are directed to the [REDACTED], specifically. And this Court’s holding focused on striking the infringement theory based on the [REDACTED] to avoid undue prejudice to Lupin from not being on notice “that they were accused of infringement due to the presence of

potentially every component of [the Markush group in Claim 1 of the '630 Patent].” D.I. 801 (explaining that “allowing this new contention now would unduly prejudice Lupin. . .”).

Ignoring the language of the Order (as well as the relief it actually requested in its motion), Lupin argues that because its letter brief once more broadly requested “that any expert opinions relating to, or alleging the presence of, the [REDACTED] in Lupin’s ANDA products be stricken” (D.I. 748 at 5), it is improper to reference the presence of the [REDACTED] in expert reports for another purpose. But Lupin’s motion itself requested narrower relief (D.I. 747 at 1) –that the untimely assertion of “new patent claims directed to the [REDACTED] . . . should be stricken.” D.I. 748 at 3. And this Court did not rule that Plaintiffs could not discuss the presence of the [REDACTED] in Lupin’s ANDA Product for any purpose whatsoever.

In fact, Lupin’s far-reaching interpretation of this Court’s Order cannot be sustained under the law. Under Rule 26(a)(1)(B), evidence that will be used “solely for impeachment” is exempt from initial disclosures, so the Court’s Order striking the addition of new claims under Rule 37(c)(1) did not strike evidence that Plaintiffs intend to use for impeachment purposes. Likewise, because a party that adequately discloses a theory of infringement is not required to list in its contentions every “item of proof” that supports that theory, the Court’s Order cannot be fairly read as restricting Plaintiffs from offering items of proof supporting their timely infringement theories. *Oracle*, 2011 WL 4479305, at *3. As a result, this Court’s Order did not restrict rebuttal evidence or otherwise limit the items of proof that Plaintiffs can put forward to rebut Lupin’s positions on their timely-asserted claims.⁴

IV. Attorney’s Fees Are Not Warranted

For the reasons set forth above, Lupin’s position is incorrect. In the event this Court disagrees, however, there is no basis for an award of fees. As noted above, Plaintiffs informed Lupin that they understand the Court’s Order to preclude Plaintiffs from asserting the [REDACTED] infringement theories. Consistent with that Order, [REDACTED] of the '630 Patent were not asserted on reply and Plaintiffs confirmed to Lupin during their meet and confer that they would not assert that the [REDACTED] infringes the asserted claims, in compliance with the June 25 Order. There is simply no evidence of bad faith as a result of Plaintiffs’ submission of a reply report responding to assertions by Lupin’s expert that Lupin’s ANDA Product does not include [REDACTED] of vortioxetine hydrobromide.

V. Conclusion

For the reasons set forth above, Lupin’s motion should be denied.

⁴ Although the risk of confusion from the limited use of the [REDACTED] evidence for proper purposes is minimal in a bench trial (and although more properly the subject of a motion in limine than a motion to strike), Plaintiffs have no objection to referring to the [REDACTED] by a pseudonym if that allays any concerns about the scope of use of the evidence.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

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Enclosures

cc: Counsel of Record (*via* electronic mail)

EXHIBITS 1-3
REDACTED IN THEIR ENTIRETY